## REMARKS

This response addresses the issues raised by the Examiner in the Office Action mailed March 25, 2004. Initially, Applicants would like to thank the Examiner for the careful consideration given in this case. The Claims were 1-20. Claims 1, 12 and 13 have been currently amended. Thus, Claims 1-20 are pending in this case all to more clearly and distinctly claim Applicants' invention. In view of the above amendments and the following remarks, Applicants submit that the presently pending claims are in condition for allowance and notification of such is respectfully requested.

**Rejection Based Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects Claims 2-4, 8, 9, 13, 17 and 18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, the Examiner states that Claims 2-4, 8, 9, 13, 17 and 18 recite the limitation solation agent. The Examiner argues that there is insufficient antecedent basis for this limitation in the claims because Claim 1 recites the limitation "solating agent" as opposed to solation agent.

In order to expedite prosecution, Claim 1 has been amended to replace the term "solating agent" with the term "solation agent" to address Examiner's rejections. Applicants submit that the claims as amended overcome the Examiner rejections under 35 U.S.C. § 112, second paragraph.

The Examiner also argues that Claim 12 is indefinite because it is a device claim depending from a method claim. Thus, the Examiner argues it is unclear whether all the elements of the device in the method claim are required by Claim 12.

In order to expedite prosecution, Applicants have amended Claim 12 to address Examiner's rejections. Applicants submit that the claims as amended overcome the

Examiner rejections under 35 U.S.C. § 112, second paragraph.

**Rejection Based On Strahilevitz Under 35 U.S.C. § 102 (b)**

The Examiner rejects Claims 1 and 2 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 4,620,977 to Strahilevitz. Applicants respectfully traverse this rejection.

To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. Strahilvitz discloses an immunoassay methods of psychoactive drugs including both agglutination and agglutination-inhibition reactions. See Abstract. Strahilvitz teaches that agglutinable carrier bound antibody in suspension is mixed with a sample, then the agglutinable carrier antibody is mixed with a free antibody to the hapten. See Strahilvitz at Col. 3, lines 17-21. So if the sample contains above a minimal amount of the free hapten, agglutination results. See Specification at col. 3, lines 17-21. However, Strahilvitz does not teach a non-fluid substance that retains particles while suppressing the diffusion of particles. Instead, Shrahilvitz teaches a matrix that may be the wall of a plastic column. See Strahilvitz at Col. 11 and 12, lines 67-68 and lines 1-2, respectively. In addition, Shrahilvitz does not teach contacting the mixture of particles and non-fluid substance with a solation agent for increasing the fluidity of the non-fluid substance in the mixture. Further, Shrahilvitz does not even mention that the non-fluid substance liquefies to enhance the diffusion of particles. Thus, Shrahilvitz does not disclose, teach or suggest the agglutination assay method of the present invention.

The present invention claims an agglutination assay method for quantitative determination of an analyte in an aqueous sample using particles bearing an anti-analyte. The anti-analyte of the present invention can bind to the analyte so as to cause agglutination of the particles. In the present invention, a mixture of particles and non-fluid substance which retains the particles while suppressing diffusion of the particles is provided. Then, the mixture comes into contact with a solation agent for increasing the fluidity of the non-fluid substance in the mixture. The non-fluid substance liquefies to enhance the diffusion of

particles. The sample then contacts the mixture to cause agglutination of the particles in the mixture which is measured to determine the amount of analyte in the sample.

Shrahilvitz does not disclose a mixture of particles and non-fluid substance which retains the particles while suppressing diffusion of the particles where when the solation agent is added to the mixture it liquefies the non-fluid substance to enhance the diffusion of particles. Since Strahilevitz does not disclose this feature of the present invention, Strahilevitz does not disclose each and every claim element of the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

**Rejection Based On Obviousness-Type Double Patenting**

The Examiner rejects Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,531,323. The Examiner claims that although the conflicting claims are not identical, they are not patentably distinct from each other because the '323 Patent claims an apparatus having particles, non-fluid substance, and a layer with a solation agent and their intended use, and the claims of the current application claims the method of using the apparatus of Patent '323. Thus, the Examiner argues that the method claims of the current application would have been obvious from the claimed apparatus and intended us of '323 Patent.

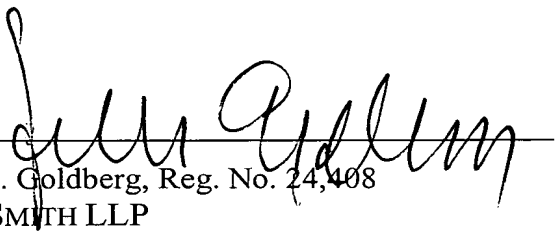
The Applicants respectfully submit that the Examiner is incorrect in requiring the Applicants submit a Terminal Disclaimer in the case. In the prosecution of '323 Patent, Examiner Goldberg issued a Restriction Requirement on October 1, 2001 requiring the Applicants to choose between Group I claims drawn to an agglutination assay for quantitatively determining an analyte in an aqueous sample and Group II claims drawn to an dry analysis element. In response to the Restriction Requirement, Applicants choose to pursue Group II claims and file the present divisional application to pursue Group I claims on October 19, 2001. Accordingly, Applicants respectfully request that the obviousness-type

double patenting rejection is improper and should be reconsidered and withdrawn.

In view of the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Respectfully submitted,

Dated: August 31, 2004

By 

Jules. E. Goldberg, Reg. No. 24,408
REED SMITH LLP
599 Lexington Avenue
29th Floor
Original York, NY 10022-7650
(212) 521-5400
Attorney for Applicant